Minimally Invasive Robotic Colon Surgery

Carol Sawmiller, M.D., F.A.C.S.
Kettering Physician Network
November 18, 2016

Learning Objectives

Discuss local and national trends and experience with robot-assisted colon surgery.

Understand the benefits of robot-assisted colon surgery.

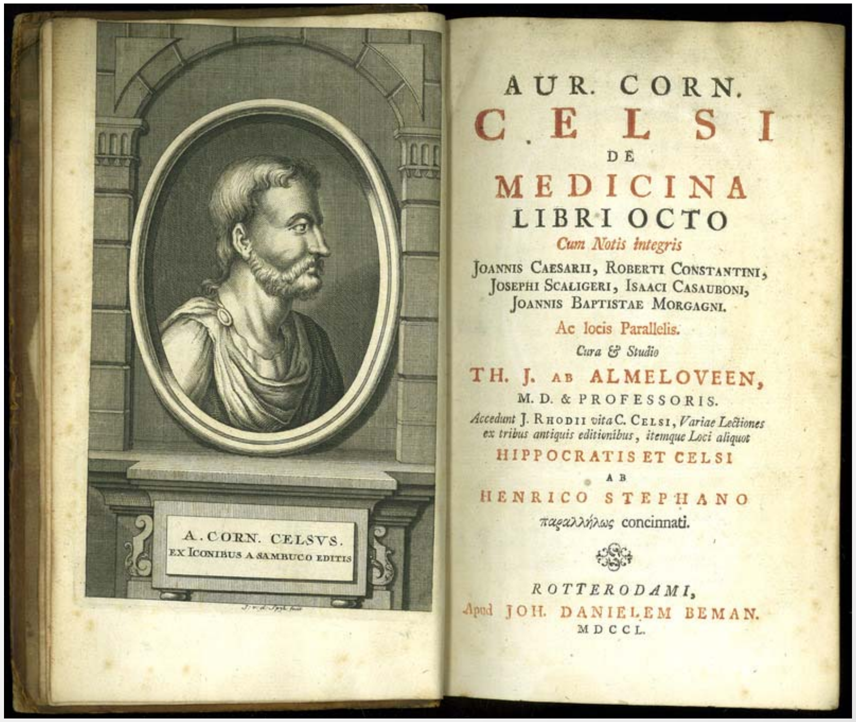
Determine which patients are good candidates for referral for robot-assisted colon surgery.

Origins of Minimally Invasive Surgery

- Endoscopic instruments described as early as 2640 BC
  - Egypt
  - China
  - India
- Hippocrates describes anoscopy with cautery of hemorrhoids   400 BC
- Surgical instruments resembling laparoscopic trocars recovered from Roman ruins

Origins of Minimally Invasive Surgery

- Aulus Cornelius Celsus
- 25 BC to 50 AD
- Roman medical scholar and writer, ?? doctor
- De medicina octo libri
- Described placing a lead or copper cannula into the peritoneal cavity to drain bad humors
- Cauterize wound to close



Origins of Minimally Invasive Surgery

- Albukasim, Arabian physician 936–1013 AD
  - Speculum using reflected light from flame
  - “Exploring needle with groove” mounted on handle allowed access to the peritoneal cavity
- Dimitri Ott, German gyn 1901
  - “Ventroscopy”
  - Introduced speculum through a posterior vaginal incision to view the pelvis
- George Kelling, German surgeon 1901
  - “Celioscopy”
  - Used a cystoscope inserted into an insufflated abdomen in an animal model

Origins of Minimally Invasive Surgery

- Jacobeus, Swedish surgeon 1910
  - First human celioscopy
  - To evaluate patients with ascites
- Bertram M Bernheim, United States 1911
  - Published his series of laparoscopic experience
  - “Organoscopy”, *Annals of Surgery*
- George Kelling reported his 22 years of experience to German Surgical Society in 1923
- World War I and II

Origins of Minimally Invasive Surgery

- 1938, Veress designs the needle entry/insufflation technique
- 1952, quartz rod used to transmit high intensity light to end of scope
- 1959, television image, monitor
- 1970's, laparoscopy widely used by gyn
- 1982, laparoscopic liver biopsy
- 1987, first lap chole done in France
- 1989, first lap colon resection

Acceptance of MIS

- Obstacles to adoption of laparoscopy:
  - It costs too much!
  - It takes too long!
  - Lap surgery cannot be as good as open!
    - Concerns about cancer surgery.
      - Adequate margins.
      - Adequate lymph node harvest.
      - Adequate exploration of peritoneal cavity.
- Thousands of studies now comparing outcomes.
- Laparoscopic surgery has proven to be superior to open for most indications.

Benefits of MIS

- Laparoscopic surgery has been shown to:
  - Shorten hospital stays
  - Decrease pain
  - Provide patients with a more rapid recovery
  - Decrease complication rate
  - Decrease re admission rate
  - Have equivalent oncologic outcomes
    - with exception of rectal cancer

- Numerous studies show decreased overall cost

MIS as New Standard of Care

- Cholecystectomy
- Appendectomy
- Bariatric surgery
- Hysterectomy
- Oophorectomy
- Endometriosis
- Adrenal surgery
- Splenectomy
- Nissen wrap
- Heller myotomy

- ?Right colectomy
- ?Left colectomy
- ?Low anterior resection
- ?Liver resections and ablations
- ?Nephrectomy
- ?Pancreaticoduodenectomy

Shortcomings of Laparoscopic Surgery

- Operate in 3D space with a 2D view – unstable visualization
- Reduced dexterity – lack of precision
- Limitations of surgeon flexibility and reach – awkward posturing
- Long and unstable instruments magnify natural tremors

Laparoscopic Instruments

Technologic Advances

- Need for better technology to allow more complex cases to be done minimally invasively.
- Lap prostatectomy never was widely adopted.
  - Limitations of working in narrow male pelvis
  - Poor visualization
  - Instrumentation
- Robot-assisted laparoscopic surgery.
  - FDA approved 2000
  - Moved prostatectomy to an MIS procedure
  - Now robot-lap is standard for prostatectomy

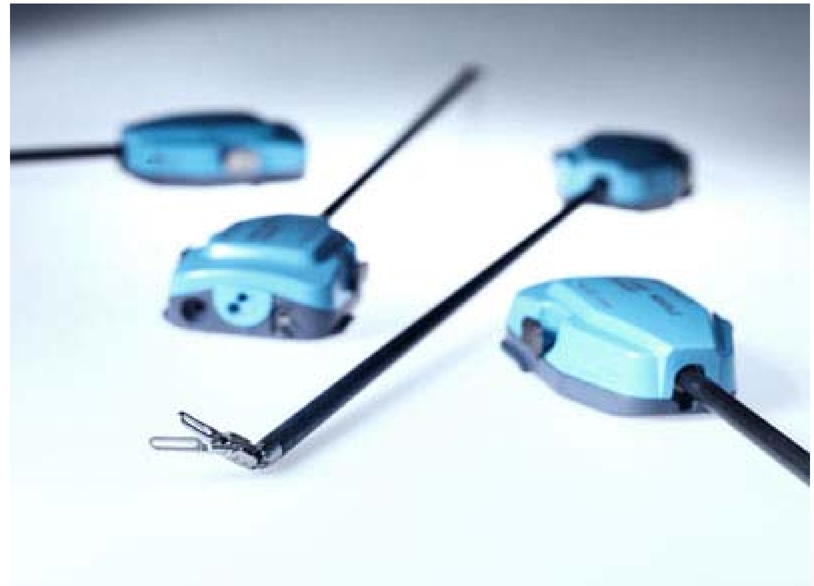
What is Robotic Surgery?

- Laparoscopic minimally invasive surgery.
- Robot is a laparoscopic tool.
- Surgeon introduces ports and docks robot to ports, allowing instrument placement.
- Surgeon controls all aspects of instrument movement.
- Carries all the risks of any laparoscopic procedure.
- Increasing the complexity of cases that can be done minimally invasively.

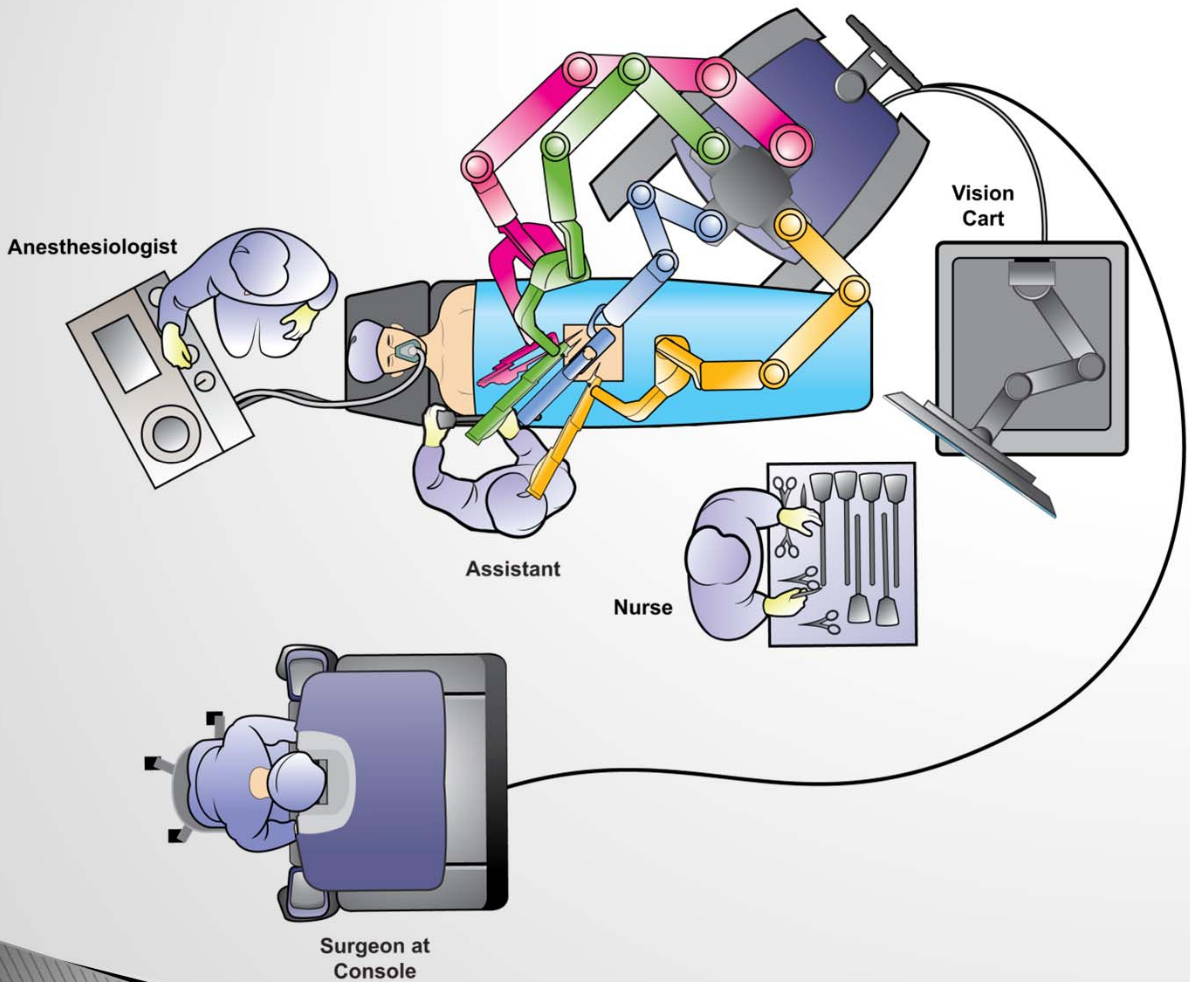
Surgery: *da Vinci®* Surgery

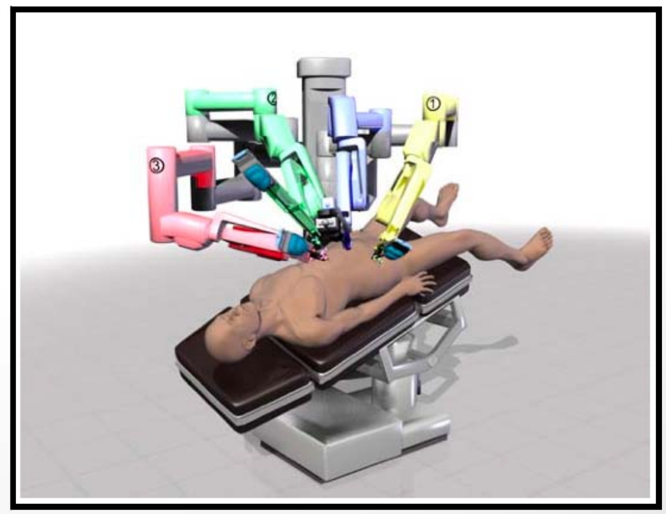
PN 875128 Rev A 2/12

Robotic Instruments

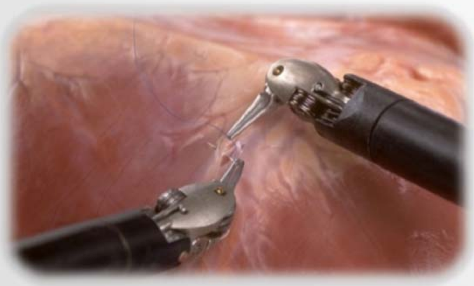


Room set up for Robotic Surgery





da Vinci® Surgery



- Surgeon is immersed in a 3D-HD surgical field with up to 10x magnification
- Surgeon directs every move of the tiny instruments using console controls
- Robotic system scales and replicates surgeon's hand movements while minimizing hand tremors
- Allows surgeon to operate with increased dexterity & precision

Acceptance of Robotic Assisted MIS

- Obstacles to adoption of robotic surgery:
  - It costs too much!
  - It takes too long!
  - Robotic surgery cannot be as good as lap!
    - Concerns about cancer surgery.
      - Adequate margins.
      - Adequate lymph node harvest.
      - Adequate exploration of peritoneal cavity.
- Studies now comparing outcomes.
- Robot-assisted surgery is proving to be equal or superior to lap for many indications.

Robotic MIS – Rectal Cancer

- Lap rectal resection has not been consistently shown to be equal to open – TME quality
- Can we do a better TME robotically?
- Robot assisted-lap surgery allows surgeon to do an intact TME

	Laparoscopic	Robotic
5 year DFS	76.0%	76.8%
Local recurrence	6.3%	2.7%
Systemic recurrence	18.9%	15.6%

Lim DR, et al. Long term oncological outcomes of robotic versus laparoscopic total mesorectal excision of mid-low rectal cancer following neoadjuvant chemoradiation therapy. Surg Endosc 2016

Robotic MIS – Rectal Cancer

- Meta analysis of robotic versus laparoscopic
  - 854 patients
  - Robotic surgery had lower rate of:
    - Conversion to open
    - Complications
    - Length of stay
      - Trastulli S., et al. Robotic resection compared with lap rectal resection for cancer. Colorect Dis. 2012 Apr;14(4):134
- Difficult patient – rectal resection in obese
  - 82 patients
  - More pronounced benefit to robotic surgery
  - Complication 9.4 % compared to 23.9% in lap
  - Decreased blood loss and length of stay

Shiomi A, et al. Robot-assisted versus lap surgery for lower rectal cancer: impact of obesity. Int J Colorect Dis. 2016 Oct;31(10):1701

Robotic MIS – Rectal Cancer

- Open TME vs Robotic TME for rectal cancer
- 5 year follow up data
  - Ghezzi, T.L., et al. Robotic versus open total mesorectal excision for rectal cancer: Comparative study of short and long-term outcomes. *Eur J of Surg Onc (EJSO) 2014*; 40(9):1072-1079.
- Equivalent outcomes for:
  - Disease free survival
  - Overall survival

	Open	Robotic
Number of LN's	14.1	20.1
Est blood loss	150 mls	Less than 10 mls
OR time	207.5 min	299.0 min
Length of stay	9 days	6 days
Local recurrence	16.1%	3.4%

Conversion to Open Rectal Resection Has Significant Implications for Patient Outcomes

	Conventional Lap	Conventional Lap Converted to Open	p value
Transfusion Rate[1] (n=300)	2%	12%	0.001
Wound Infection Rate[1] (n=300)	12%	23%	0.01
Complication Rate[2] (n=1,073)	21%	44%	<0.001
Length of Stay Increase[2] (n=1,073)	Base	+ 6 days	0.01
5-yr Disease-Free Survival Rate[3] (n=450)	70%	40%	0.011

Study limitations: multiple studies, none are randomized trials; outcomes may vary subject to the surgeon's prior laparoscopic experience and training

1. Agha, et al. Conversion rate in 300 laparoscopic rectal resections and its influence on morbidity and oncologic outcome. Intl J of Colorectal Disease. 2008 Apr;23(4):409-17.
2. Yamamoto, et al. Impact of Conversion on Surgical Outcomes after Laparoscopic Operation for Rectal Carcinoma: A Retrospective Study of 1,073 patients. Journal of American College of Surgeons. 2009 Mar;208(3):383-9.
3. Rottoli, et al. Laparoscopic Colorectal Resection for Cancer: effects of conversion on long-term oncologic outcomes. Surgical Endoscopy. 2012 Jul;26(7):1971-6

Initial Clinical Data for dV in Rectal Cancer is Promising

	Patient Population	Positive CRM, %	Conversion Rate, %	LOS days	Complication Rate, %
Pigazzi (2006)[1]	6	NR	0.0	4.5	1
Hellan (2007)[2]	39	0.0	1.0	4.0	5
Baik (2008)[3]	18	NR	0.0	7.0	4
Patriti (2009)[4]	29	0.0	0.0	11.9	7
Baik (2009)[5]	56	7.1	0.0	5.0	3
Park (2010)[6]	41	1.9	0.0	9.9	12
Pigazzi (2010)[7]	143	0.7	7.0	9.3	59
Bianchi (2010)[8]	25	0.0	0.0	6.5	4
Baek (2010)[9]	64	0.0	6.0	5.0	23
Baek (2011)[10]	41	2.4	3.0	6.5	9
Kwak (2011)[11]	59	1.7	0.0	NR	19
Park (2011)[12]	52	2.4	0.0	10.0	10
Kang (2013)[13]	165	4.2	0.6	10.8	21
D'Annibale (2013)[14]	50	0.0	0.0	8.0	10
da Vinci®	788	2.1%	2.1%	8.2	22%
MRC Classic[15]	242	16.0	34.0	10.0	32
COLOR II[16]	739	10.0	17.0	8.0	49
Lap	981	11.0%	21.0%	8.5	38%
MRC Classic[15]	132	14	N/A	13.0	37
COLOR II[16]	364	10	N/A	9.0	37
Open	496	11.0%	N/A	10.1	37%

Studies selected based on highest quality of available literature; no statistical analysis has been performed; analysis may confirm that numerical differences are not statistically significant.

Initial Clinical Data for dV in Colon Surgery is Promising

	Patient Population	EBL, mL	Conversion Rate, %	Complication Rate, %
Weber (2002)[17]	2	NR	0.0	0.0
Delaney (2003)[18]	5	140	9.6	20.0
D'Annibale (2004)[19]	53	21	9.4	7.5
de Noto (2006)[20]	11	NR	9.1	NR
Rawlings (2007)[21]	30	62	6.7	15.7
Spinoglio (2008)[22]	50	NR	4.0	14.0
de Souza (2010)[23*]	40	50	2.5	20.0
Park (2012)[24]	35	36	0.0	17.1
da Vinci®	**226**	**42**	**5.1%**	**14.3%**
COLOR Trial[25]	534	100	17.0	21.0
COST Trial[26]	435	N/A	21.0	21.0
MRC CLASSIC[15]	185	N/A	25.0	26.0
Laparoscopy	**1154**	**100**	**19.8%**	**21.8%**

Studies selected based on highest quality of available literature; no statistical analysis has been performed; analysis may confirm that numerical differences are not statistically significant.

NSQIP Data – Colectomy

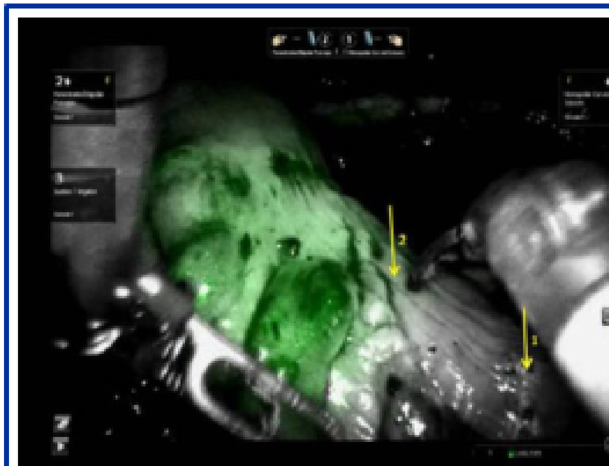
- American College of Surgeons NSQIP
- 387 pts per group – open, robot, lap
- Operative time longer in robotic cases
- Lower in robotic:
  - Length of stay
  - Overall morbidity
  - Superficial SSI
  - Blood loss/transfusion
  - Ventilator dependence post op
  - Ileus
    - Benlice C, et al. Robotic, lap and open colectomy: a case-matched comparison from ACS-NSQIP. Int J Med Rob. 2016 Oct

Firefly™ Shows Trend Toward Reduction in Leak Rate

The use of indocyanine green fluorescence to assess anastomotic perfusion during robotic assisted laparoscopic rectal surgery*

Mehraneh D. Jafari · Kang Hong Lee · Wissam J. Halabi ·
Steven D. Mills · Joseph C. Carmichael · Michael J. Stamos ·
Alessio Pigazzi

	Firefly Group (*n*=16)	Non-*Firefly* Control Group (*n*=22)
Revision of Transection Point	19%	5%
Anastomotic leak rate	6%	18%
Diversion (Temporary Stoma)	75%	77%
Median level of anastomosis	3.5 cm	5.5 cm



Example of revised transection point

Study limitations: retrospective non-randomized study design may result in sampling bias; no statistical analysis was performed

Jafari et al., "The use of indocyanine green fluorescence to assess anastomotic perfusion during robotic assisted laparoscopic rectal surgery." Surg Endosc 2013 Aug; 27(8): 3003-8.

Ongoing Level I Randomized Clinical Trial

ROLARR

- Grant from Efficacy and Mechanism Evaluation Programme from the Medical Research Council, part of the UK's National Institute for Health Research
- Randomized multi-center, international trial for robotic vs laparoscopic surgery
- Enrolling a total of 400 patients
- Primary endpoints:
  - Conversion
  - Cancer outcomes
- Secondary endpoints:
  - Safety, Functional, Oncological, Quality of life, Health Economics, GOALS Score
- Expecting completion of enrollment by Sept 2014

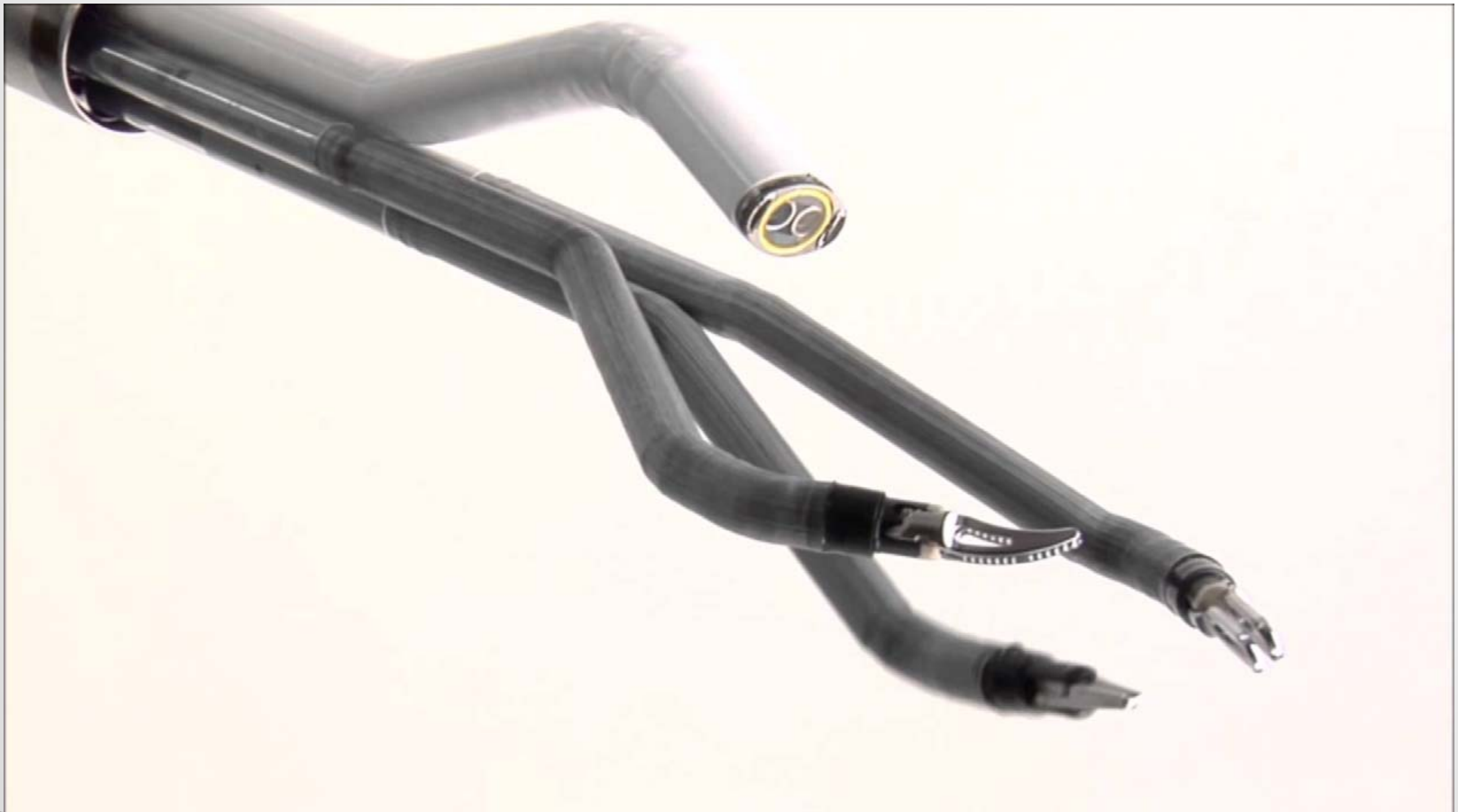
For more information, visit www.clinicaltrials.gov.

INTUITIVE SURGICAL®

da Vinci Surgery

PN 1005166 Rev A 1/14

Next Generation



National Trends in Colorectal Surgery

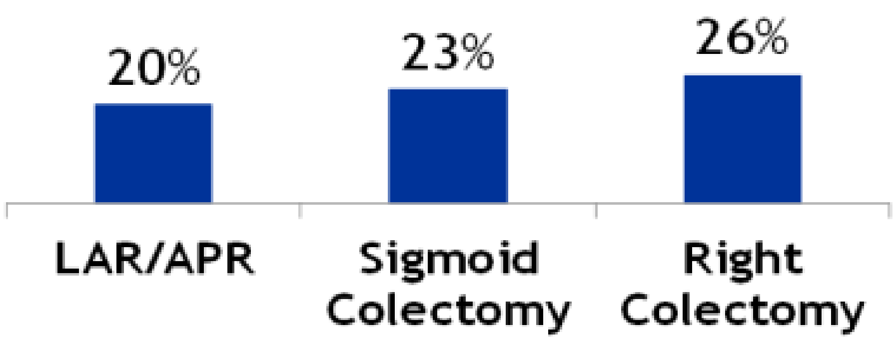
- National Inpatient Sample database
- 2009 – 2012
- 509,029 patients undergoing colectomy
  - 52.3% open
  - 46.2 % laparoscopic
  - 1.5% robotic
- Trend toward higher volume centers doing higher percentage of MIS
- Robotic cases quadrupled from 2009 to 2012

Yeo HL, et al. Comparison of open, laparoscopic, and robotic colectomies using a large national database. Dis Col Rect 2016 Jun;59(6):535.

Adoption of MIS is Limited, Even Among Fellowship Trained Surgeons & Regardless of Procedure Type

The impact of practice environment on laparoscopic colectomy utilization following colorectal residency: a survey of the ASCRS Young Surgeons

Scott R. Steele*, Sharon L. Stein†, Liliana G. Bordeianou‡, Eric Johnson§, Dan O. Herzig¶ and Bradley J. Champagne† on behalf of the American Society of Colon and Rectal Surgeons' Young Surgeons Committee



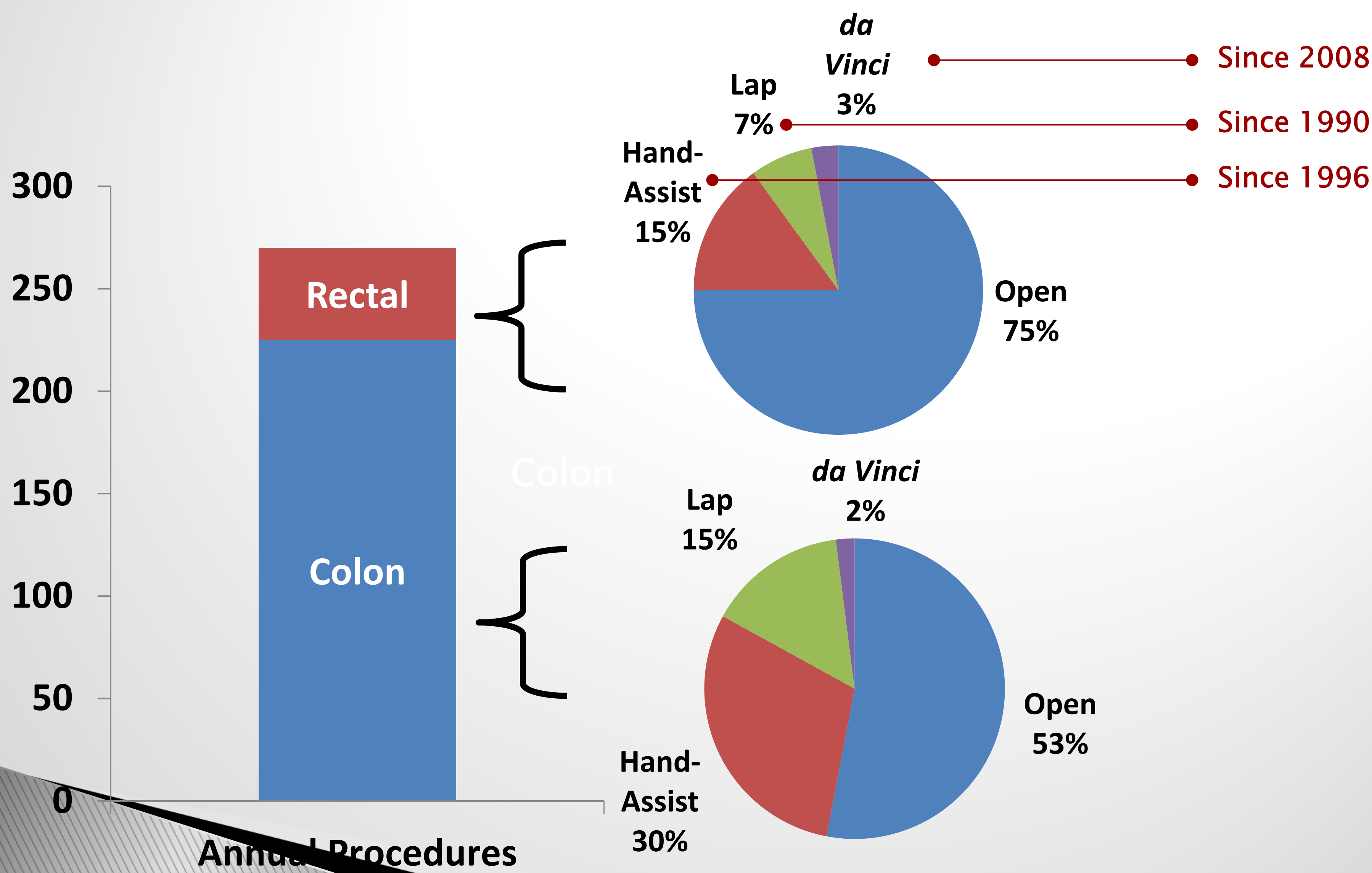
Reasons Provided:

1) Inappropriate Patients
2) Lack of Qualified Bedside Assist
3) Personal Comfort / Experience

Study limitation: Survey study design has inherent sampling biases.

Steele, et al. "The impact of practice environment on laparoscopic colectoomy utilization following colorectal residency: a survey of the ASCRS young surgeons." Colorectal Dis 2012 Mar; 14(3): 374-81.

Few Surgeons Offer Advanced MIS Surgery



Financial Incentive to Surgeon?

- No separate billing codes for robotic surgery.
- Procedures generally take longer.
- Financial disincentive to robotic surgery

	Open (RVU's)	Lap (RVU's)
Low Anterior Resection	28.58	31.92
Partial Colectomy	22.59	26.42
Right Colectomy	20.89	22.95
Mobilize Splenic Flex	2.23	3.50

Overall Cost

- Cost analysis review of 227 patients
  - Robotic – 96
  - Laparoscopic – 131
- Pathology, complications, readmission,30 day mortality similar in this study

	Laparoscopic	Robotic
OR time	113 min	109 min
Length of stay	6.6 days	5.7 days
Conversion	6%	13%
Cost	114,853.00	107,220.00

Vasudevan V, et al. Clinical outcomes and cost-benefit analysis comparing lap and robotic colorectal surgeries. Surg Endosc 2016 Apr;

dV Colorectal Surgery Financials

Reduced LOS and Complications Help Reduce Cost and Increase Profits

Roper Hospital Economics Data, 2012

Procedure		#	Time (min)	LOS (days)	Avg Direct Supply Cost	Avg. Net Profit
Diverticulitis	Robotic	19	131	4.2	$3,863	$12,960
	Lap.	70	122	5.3	$1,809	$11,541
	Open	7	157	12.7	$1,336	$5,297
Rectal Cancer	Robotic	13	145	4.2	$3,863	$10,994
	Lap.	5	154	7.2	$2,987	$3,877
	Open	1	157	12.7	$1,463	$547

Data should be considered preliminary until published in a peer-reviewed journal; no statistical analysis has been performed

Provided courtesy of Jorge Lagares-Garcia, MD and Roper Hospital (Charleston, SC)

Cost Implications of MIS

- Projected cost analysis
- If all hospitals increased MIS to the level of the top 1/3 of hospitals
- 7 most common complications
  - Makary, M. et al. Hospital Cost Implications of Increased Use of Minimally Invasive Surgery. JAMA Surgery, Mar 2015

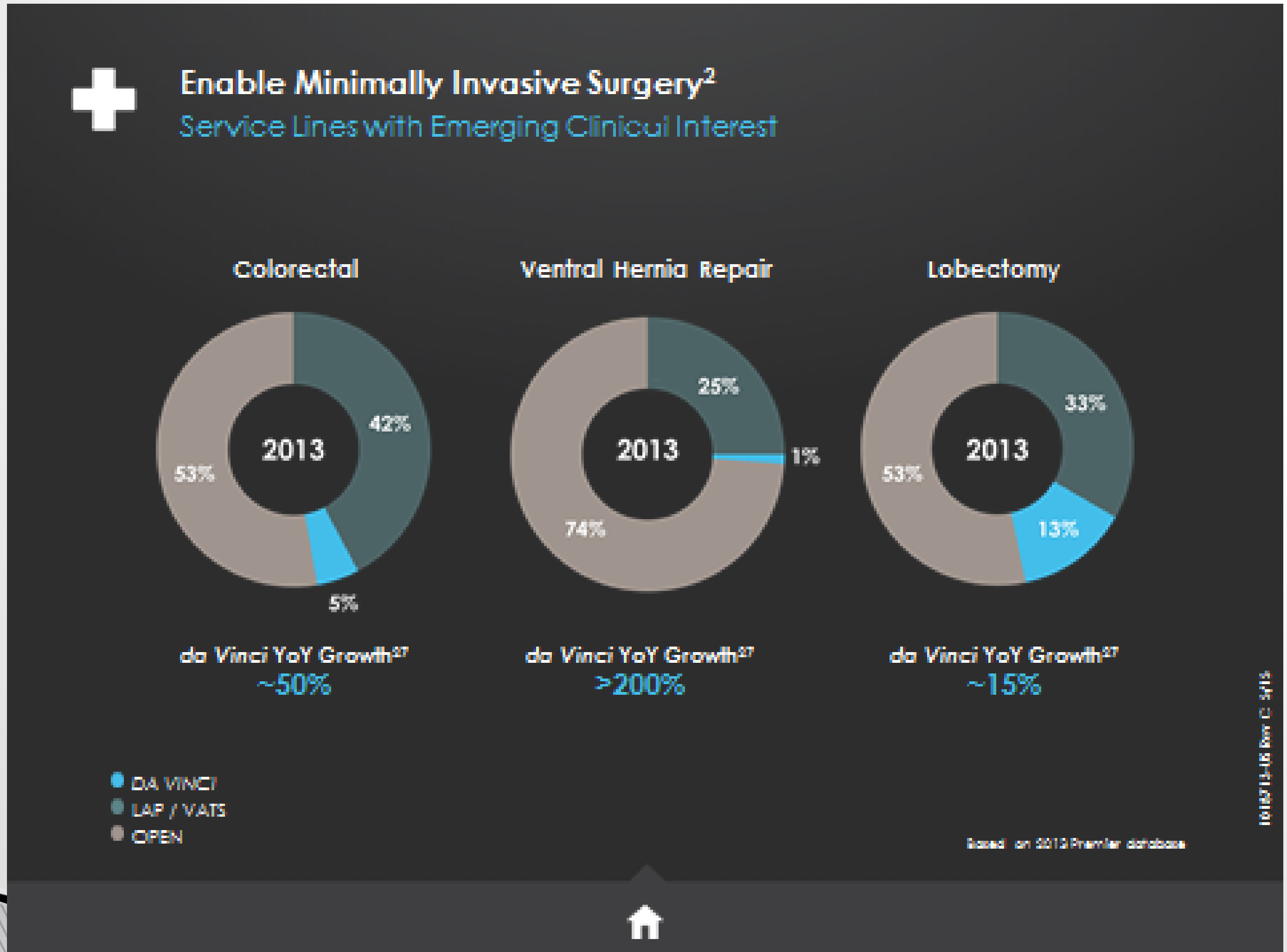
	Colectomy	Appendectomy
Length of stay, days	−3.0	−1.4
Savings per case, $	7507.00	1528.00
Complications avoided	2289	1257
Hospital days avoided	91,257	60,478
COST SAVINGS,$	227,875,653.00	54,834,092.00

Long Term Costs

- <u>Small Bowel Obstruction</u>
- Lap – 2.4%
- Open 7.3%
  - Bartels, S. A. et al. Small bowel obstruction, incisional hernia and survival after laparoscopic and open colonic resection (LAFA study). Br J Surg, 101: 1153-1159.
- Early (within 30 days)
  - Lap 5%
  - Open 8%
- Late
  - Lap 2%
  - Open 4.5%
  - Yamada T,et al. Meta-analysis of the risk of small bowel obstruction following open or laparoscopic colorectal surgery. Br. J. Surg. 2016;103:493

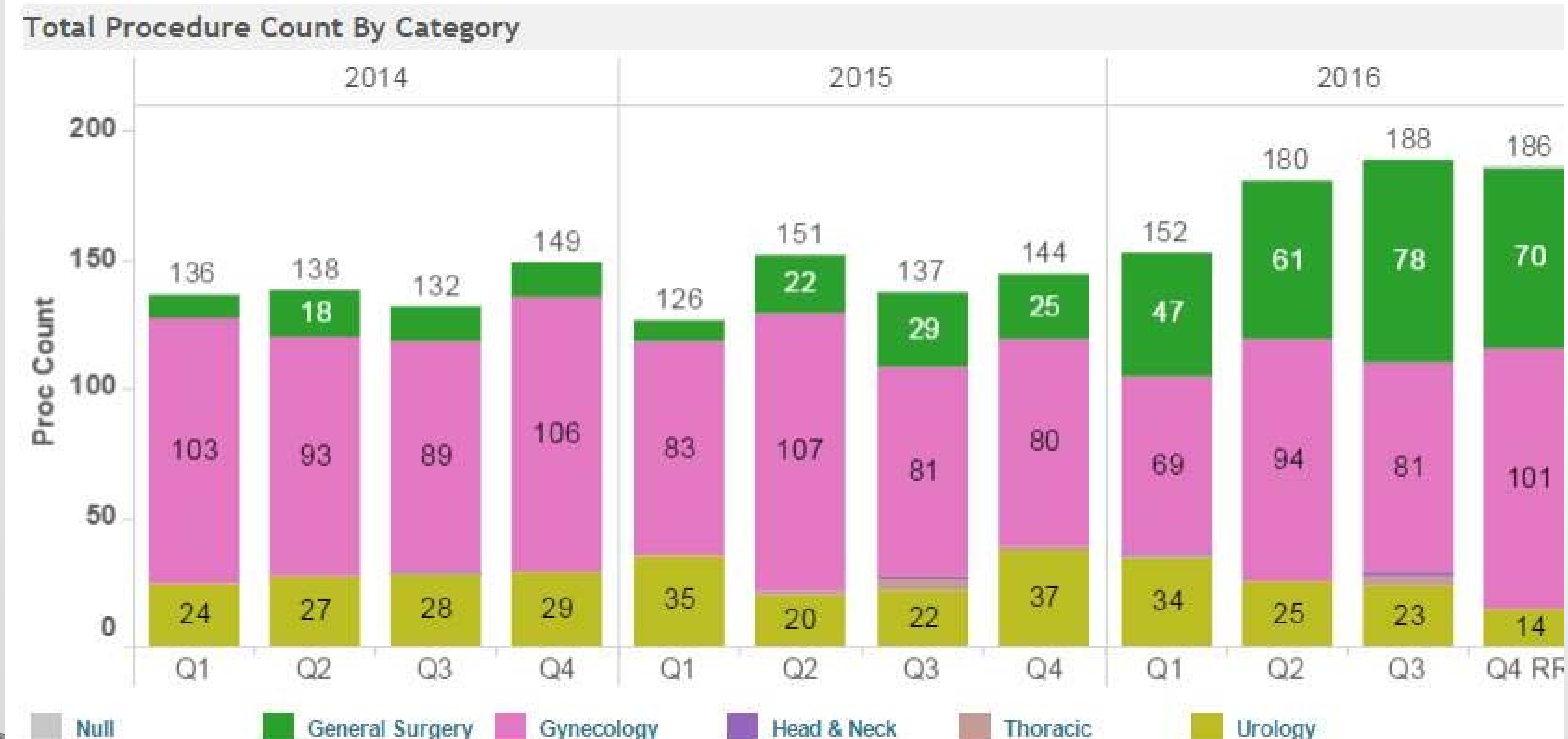
- <u>Incisional Hernia</u>
- 10-25% rate currently
- Lap – 10.1 %
- Open – 16.7 %
  - Bartels, S. A. et al. Small bowel obstruction, incisional hernia and survival after laparoscopic and open colonic resection (LAFA study). Br J Surg, 101: 1153-1159.
- CLASICC Trial
  - Decreased incis hernia rate with MIS.
  - Taylor GW. Br. J. Surg. 2010; 97(1):70.
- COLOR Trial
  - Decreased rate of incis hernia with lap surgery

KHN Data



Enable Minimally Invasive Surgery[2]
Service Lines with Emerging Clinical Interest
Colorectal
2013
42%
53%
5%
da Vinci YoY Growth[27]
~50%
Ventral Hernia Repair
2013
25%
1%
74%
da Vinci YoY Growth[27]
>200%
Lobectomy
2013
33%
53%
13%
da Vinci YoY Growth[27]
~15%
DA VINCI
LAP / VATS
OPEN
Based on 2013 Premier database

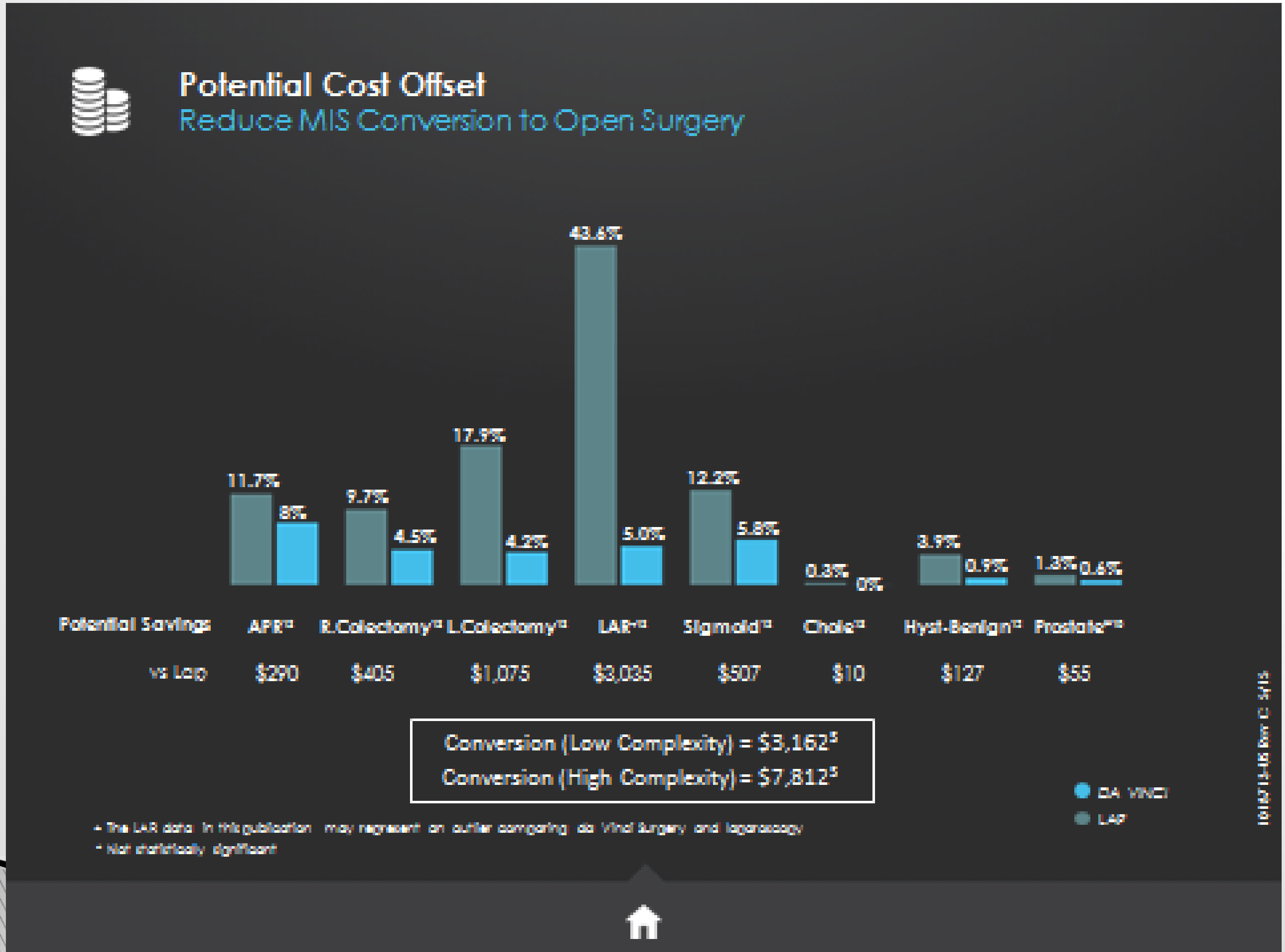
KHN Robotics Program



KHN Data


Potential Cost Offset
Reduce Length of Stay (Days)
7.3
5.3
3.2
2.7
1.8
1.3
3.6
2.4
1.7
3.1
2.1
1.4
9.4
6.0
4.8
Potential Savings
Lobectomy[9]
Prostatectomy[10]
Hyst-Malignant[11]
Hyst-Benign[12]
Colon Resection[2]
vs Open
$6,367
$2,640
$2,951
$2,174
$7,144
vs Lap
$3,261
$1,087
$1,087
$777
$1,864
Hospital Day (General Ward) = $1,553[4]
DA VINCI
LAP
OPEN

KHN Data



Potential Cost Offset
Reduce MIS Conversion to Open Surgery
43.6%
17.9%
11.7%
8%
9.7%
4.5%
4.2%
5.0%
12.2%
5.8%
0.3%
0%
3.9%
0.9%
1.3%
0.6%
Potential Savings vs Lap
APR
R.Colectomy
L.Colectomy
LAR
Sigmoid
Chole
Hyst-Benign
Prostate
$290
$405
$1,075
$3,035
$507
$10
$127
$55
Conversion (Low Complexity) = $3,162
Conversion (High Complexity) = $7,812
DA VINCI
LAP
The LAR data in this publication may represent an outlier comparing da Vinci Surgery and laparoscopy
Not statistically significant

Who is Appropriate for referral for MIS Robotic Colon Surgery?

- Everyone!!
  - Goal to achieve MIS for as many patients as possible
  - Robotic surgery may allow more patients to benefit
- Recurrent diverticulitis
  - Stricture
  - Chronic LLQ pain, difficulty passing stool
  - Colovesicular/colovaginal/coloenteric fistula
- Polyps not amenable to endoscopic removal
- Need for diverting colostomy
- Crohn's disease, Ulcerative Colitis
- Colon Cancer, Rectal Cancer

Who may not be a good candidate?

- Anything that precludes laparoscopy
  - Known extensive adhesions
  - Inability to tolerate pneumoperitoneum
  - Large bulky tumor or need for en bloc resection with adjacent organs
- ?Emergent Cases
  - GI bleed with hemodynamic instability
  - Perforated colon with peritonitis
  - Ischemic colon
  - Limited by robot/staff availability
  - Limited by patient instability, need for quickest intervention

Minimally Invasive Robotic Colon Surgery

- Achieve oncologic outcomes equal to or better than lap or open
- Decreased complications
- Improved patient satisfaction
  - Reduced pain
  - Reduced length of stay
  - Quicker return to work/activity
- Quicker learning curve for surgeon
- Able to do more complex cases
- Proving to be financially beneficial to Healthcare System

QUESTIONS ???